NT Health
Research Governance Office (RGO)
Site Specific Assessment (SSA)

Completion Guide

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| 1.0 | 30/09/2020 | Jane Nelson | Initial draft |
| 2.0 | 07/03/2022 | Fransisca Tenorio | Reflecting all changes made to the SSA Form |

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| Acronyms | Full form and definition |
| RGO | Research Governance Office |
| SSA | Site Specific Assessment |
| NT | Northern Territory |
| PI | Principal Investigator |
| HREC | Human Research Ethics Committee |
| NMA | National Mutual Acceptance |
| NHMRC | National Health & Medical Research Council |
| FOR | Field of Research |
| AI | Associate Investigator |
| GCP | Good Clinical Practice |
| CRA | Clinical Research Associate(s) |
| WWCC | Working with Children’s Clearance |
| PHCC | Primary Health Care Centre(s) |
| PHC | Primary Health Care |
| ICU | Intensive Care Unit |
| AWCC | Alan Walker Cancer Centre |
| ECG | Electrocardiogram |
| ALO | Aboriginal Liaison Officer |
| CTN | Clinical Trial Notification |
| ARTG | Australian Register of Therapeutic Goods |
| CTA | Clinical Trial Approval |
| TGA | Therapeutic Goods Administration |
| MA | Medicines Australia |
| MTAA | Medical Technology Association of Australia |
| GMO | Genetically Modified Organisms |
| HREC | Human Research Ethics Committee  |
| CRG | Collaborative Research Group |
| PISCF | Participant Information Statement and Consent Form |

Contents

[1. Purpose of the SSA form 6](#_Toc97643942)

[2. When this form should be used 6](#_Toc97643943)

[3. Instructions for completion 6](#_Toc97643944)

[4. Completion Guidance 7](#_Toc97643945)

[4.1 Project Details 7](#_Toc97643946)

[(Q1.1) SSA Submission Date 7](#_Toc97643947)

[(Q1.2) Reviewing HREC 7](#_Toc97643948)

[(Q1.3) Project Title 7](#_Toc97643949)

[(Q1.4) Brief Summary of project 7](#_Toc97643950)

[(Q1.5) National Health & Medical Research Council (NHMRC) Broad Research Area 7](#_Toc97643951)

[(Q1.6) NHMRC Field of Research 8](#_Toc97643952)

[(Q1.7) Project Type 8](#_Toc97643953)

[(Q1.8) Anticipated Project Start and Finish Date 8](#_Toc97643954)

[4.2 Research Project Staff 8](#_Toc97643955)

[(Q2.1) NT Health Site PI 8](#_Toc97643956)

[(Q2.2) NT Health Site AI/Associate Investigator(s) 9](#_Toc97643957)

[(Q2.3) External Staff (Non-NT Health) 9](#_Toc97643958)

[(Q2.4) Conflict of interest 10](#_Toc97643959)

[(Q2.5) Staff training/credentialing 10](#_Toc97643960)

[(Q2.6) Project Coordinator/Contact Person 10](#_Toc97643961)

[4.3 Project site(s) 10](#_Toc97643962)

[(Q3.1) Project/Study site(s) 10](#_Toc97643963)

[(Q3.2) NT Health site(s) 10](#_Toc97643964)

[4.4 Participants 10](#_Toc97643965)

[4.5 Resources 11](#_Toc97643966)

[(Q5.1) Site – Hospital activities 11](#_Toc97643967)

[(Q5.2) Site – PHC activities 11](#_Toc97643968)

[4.6 Access to information and data 12](#_Toc97643969)

[4.7 Pharmacy – investigational drugs 12](#_Toc97643970)

[4.8 Radiology – medical imaging and nuclear medicine 13](#_Toc97643971)

[4.9 Pathology – Territory Pathology – NT Department of Health 13](#_Toc97643972)

[4.10 Research Agreement 13](#_Toc97643973)

[4.11 Indemnity and Insurance 14](#_Toc97643974)

[4.11.1 Indemnity – NT Health employees 14](#_Toc97643975)

[4.11.2 Indemnity - commercial sponsor 14](#_Toc97643976)

[4.11.3 Indemnity - collaborative research group 14](#_Toc97643977)

[4.11.4 Certificate of currency - requirements for all clinical trials 15](#_Toc97643978)

[4.12 Biosafety, chemical and radiation safety 15](#_Toc97643979)

[4.12.1 Regulation of gene technologies and related therapies 15](#_Toc97643980)

[4.12.2 Ionising radiation 15](#_Toc97643981)

[4.13 Funding 15](#_Toc97643982)

[4.14 Intellectual Property (IP) 16](#_Toc97643983)

[4.15 Dissemination of outcomes 16](#_Toc97643984)

[4.16 Departments/Services Endorsements 17](#_Toc97643985)

[4.17 Supporting Documents 17](#_Toc97643986)

[4.17.1 Site Specific requirements for Participant information sheet and consent form (PISCF) – NT Health RGO details 17](#_Toc97643987)

[4.18 Document submission checklist 17](#_Toc97643990)

[4.19 Declaration by Site PI 17](#_Toc97643991)

[4.20 Recommendation by most relevant 18](#_Toc97643992)

[4.21 Recommendation by relevant professional lead 18](#_Toc97643993)

[4.22 Recommendation by Institutional Head 18](#_Toc97643994)

[4.23 Final authorisation by RGO 19](#_Toc97643995)

# Purpose of the SSA form

The SSA form is an information gathering tool used to assess the research projects impact on each relevant NT Health department where the project will be conducted. The information provided will be reviewed by the appropriate authorising delegate(s) from the NT Health department to ensure that there are resources available to effectively conduct a research project at the nominated NT Health site(s). The responsible delegate will provide the research governance office with their support or a reason why the project is not supported.

The SSA enables RGO’s commitment to the research in terms of:

* Adequate resources which have been identified as appropriate, accountable and available (financial, human, equipment, consumables and infrastructure) for the research to proceed at the NT Health site(s)
* Researchers have the necessary expertise and experience to carry out the work, or have provided evidence they will undergo the relevant training before they carry out their role in the research study
* Compliance with relevant laws, policies, and codes of conduct relating to matters such as indemnity insurance, privacy, confidentiality, consent, bio-safety, professional standards, and radiation safety

# When this form should be used

All research projects conducted with NT Health staff, patients, sites and/or data, require an SSA as a component of research governance.

# Instructions for completion

The SSA must be completed by the Site Principal Investigator (PI) responsible for the research project at the nominated NT Health site(s). All questions on the form must be completed. All research projects conducted within NT Health must designate an individual, qualified by training and experience, to serve as the NT health Site PI. The PI must have sufficient authority, relevant scientific knowledge, and the requisite training to personally carry out or supervise all aspects of the project at NT Health.

The SSA should be submitted with all the supporting documents as separate attachments via email. It is the responsibility of the Site PI to provide evidence to support sections 16 and 20-22, as required. The checklist in section 18 has been designed to assist the applicant in ensuring a full and complete SSA package is submitted. Once completed, the SSA form plus electronic copies of all attachments (as listed in section 17) must be submitted separately to the RGO nthealth.rgo@nt.gov.au

The RGO will assess the submitted form and attachments. If further information is required, the Site PI will be notified by the RGO. The Site PI must receive organisational authorisation in writing from the RGO prior to commencing research project at any NT Health site(s).

Please note: The study can only commence at NT Health site once both the HREC approval and SSA authorisation have been granted.

If you are still unsure about what is required, you should seek clarification from the NT Health RGO on (08) 8922 7561 or nthealth.rgo@nt.gov.au

# Completion Guidance

## 4.1 Project Details

##  (Q1.1) SSA Submission Date

Enter the date of SSA submission to the NT Health RGO.

## (Q1.2) Reviewing HREC

Please tick all that are applicable.

The NT is a signatory to the National Mutual Acceptance (NMA) scheme. Please refer to the HREC of NT Health and Menzies School of Health Research [application process](https://www.menzies.edu.au/page/Research/Ethics_approval/3_National_Mutual_Acceptance_NMA_application_process/) for details on how to complete application.

Note that application under NMA may result in further specialist ethics review which may result in additional requirements for the project.

Note also that this process requires close and continuing communication between Coordinating Principal Investigator, Primary NMA reviewing HREC, and the NT Health RGO

For multi-centre projects that are approved under the NMA process, please add the ‘reviewing’ HREC name. NT Health site/s (i.e. Royal Darwin Hospital) needs to be added/listed as one of the study sites.

Please provide Reviewing HREC reference number.

If under NMA, please also provide NT HREC reference number (for the reciprocal approval).

## (Q1.3) Project Title

Please add the full/scientific title, short title and/or acronym of the project (if there is one).

## (Q1.4) Brief Summary of project

Please provide a brief summary of the project in plain language, this can be the same as what was added to the ethics application. Please include the research activities that will be conducted at each nominated NT Health site(s).

## (Q1.5) National Health & Medical Research Council (NHMRC) Broad Research Area

Please select appropriate answer.

**Basic Sciences** – This is any of the sciences such as anatomy, physiology, bacteriology, pathology or chemistry.

**Clinical Medicine** – Is a field of medicine that deals primarily with the practice and study of medicine based on the direct examination of the patient.

**Health Service Research** – Examines social factors, health policy, financing systems, organizational structures and processes, medical technology, and personal behaviours affect access to health care, the quality and cost of health care, and quantity and quality of life

**Public Health** – The World Health Organization defines public health as 'the art and science of preventing disease, prolonging life and promoting health through the organized efforts of society'

## (Q1.6) NHMRC Field of Research

Please click [here](https://www.nhmrc.gov.au/about-us/resources/australian-standard-research-classifications-and-research-keywords)

Please provide the Field of Research (FOR) name for the main activity of the research (e.g. Haematology, Respiratory Disease, Infectious Disease).

## (Q1.7) Project Type

Please select appropriate answer.

**Clinical trial drug** – if the project is a medicinal study then please tick this and provide the drug trial phase of the study (see [here](https://www.tga.gov.au/sites/default/files/australian-clinical-trial-handbook.pdf))

**Clinical trial device** – if the project is a clinical device then please tick this and provide the device trial phase of the study(see [here](https://www.tga.gov.au/sites/default/files/australian-clinical-trial-handbook.pdf))

**Clinical research (includes all other clinical research and clinical trials not involving drugs / devices)** – Includes all other clinical research trialling new interventions and therapies not involving drugs / devices.

**Quantitative Research** – disciplined inquiry that examines people’s lives, experiences and behaviours and the stories and meanings ascribed to them – through interviews, focus groups, observation, archival, on-line, and/or action research

**Conducting non-invasive** physical experiments or examinations

Research involving **human tissue** or **biological samples**

**Research involving human genetics** – studying the structure, location, function, expression, interaction, abnormalities and effects of the genes

Research involving **human stem cells**

Research involving **exposure to ionising radiation** (above standard of care). Please attach certificate from ionising radiation expert with this application

Establishment of or data contribution into a **Registry –** A registry is an organised system that uses observational methods to collect uniform data +/- specimens on specified outcomes in a population defined by a particular disease, condition or exposure

**Evaluation -** a form of disciplined and systematic inquiry that is carried out to arrive at an assessment or appraisal of an object, program, practice, activity, or system with the purpose of providing information that will be of use in decision making.

**Other –** please choose other if none of the above are appropriate.

## (Q1.8) Anticipated Project Start and Finish Date

This is anticipated start and finish dates at NT Health site(s). Please allow time for ethics and governance approval. Research governance approval cannot be granted retrospectively.

## Research Project Staff

## (Q2.1) NT Health Site PI

Please provide site PI details. Please refer to NT Health site PI responsibilities [here](https://health.nt.gov.au/data-and-research/nt-health-research/site-principal-investigator-responsibilities)

All research projects conducted within NT Health must designate an individual, qualified by training and experience, to serve as the NT Health Site PI. The PI must have sufficient authority, relevant scientific knowledge, and the requisite training to personally carry out or supervise all aspects of the project at NT Health. The site PI is responsible for ensuring all persons involved in the research have adequate qualifications and experience to perform delegated tasks and have received appropriate and adequate training in research-related procedures. The site PI is required to maintain an up-to-date site staff signature and delegation log in their site files that list all the research staff performing research specific activities within the study.

If site PI would perform any research activities that are outside of their scope of clinical practice, section 21 would need to be completed and signed by their authorising delegate (i.e. Executive Director of Medical Services, Executive Director of Nursing and Midwifery or Executive Director of Allied Health, etc.)

Note: Unqualified students may not be listed as PIs. Please submit a copy of the site PI’s Curriculum Vitae with the SSA application

## (Q2.2) NT Health Site AI/Associate Investigator(s)

Please list all NT Health staff that will conduct any research activities at NT Health site(s), including their research role, qualifications and division/unit that they are employed under (e.g. medicine/nursing/allied health, renal, paediatrics, etc.).

Good clinical practice (GCP) certification is a requirement for clinical trials, if you currently do not hold this or would like further information on gaining this certification please contact the research governance office for advice. The Site PI is responsible for ensuring all members of the research team undertake GCP training prior to the commencement of the study and keep a current certificate throughout the project.

Please estimate how many hours per week that this investigator is expected to actively work on the research stipulating hours that will be paid and/or unpaid (in-kind). Include in your calculation time spent on study preparation, eligibility determination, consenting, paperwork, adverse event reporting, regulatory requirements and general oversight of the study.

## (Q2.3) External Staff (Non-NT Health)

Please list all external staff that will be accessing confidential NT Health data and/or accessing NT Health facilities as part of this research project, including their research role and employer/organisation.

Please indicate what access they would require; confidential data and/or facilities.

For external staff accessing NT Health confidential data, please also sign the Deed of Confidentiality and Compliance Form.

For students undertaking any research activities as part of their student placement/training, please sign the Student Deed of Undertaking.

Non-NT Health staff and/or students may only access identifiable NT Health patient’s data and/or NT Health facilities (site) to perform specified research activities as delegated by the site PI. Authorisation for these members of the research team is gained through the site specific assessment (SSA) approval process and requires adherence to all relevant NT Health policies and guidelines.

For example, and to avoid doubt, these requirements extend to:

* any monitors, Clinical Research Associates (CRA) or other non-NT Health personnel working on the study in any capacity who have access to identifiable NT Health patient information
* any monitors, CRAs or other non-NT Health personnel working on the study in any capacity who are at any time on-site at an NT Health facility for research related purposes. An exemption can be sought for those non-NT Health staff and students who are on-site but not in a position to access any identifiable data and/or child related work.
* any researcher or research group who wishes to access NT Health data for the purposes of creating a registry and who can at any time access identifiable NT Health patient data. In this instance, every person who is non-NT Health staff or student must satisfy the above requirements if they can at any time access identifiable NT Health patient data.

It is site PI’s responsibilities to ensure that all non-NT Health staff and/or students accessing NT Health identifiable data and/or facilities must have an initial national police check (valid within six months), working with children’s clearance (WWCC) if the research involves accessing data of children under 18 years of age, evidence of indemnity, appropriate qualifications and professional registration where relevant, and up-to-date immunisation requirements as per NT Health policy. Please refer to NT Health site PI responsibilities [here](https://health.nt.gov.au/data-and-research/nt-health-research/site-principal-investigator-responsibilities)

## (Q2.4) Conflict of interest

Please declare if any researchers involved in the research project have a conflict of interest. If yes, please complete Conflict of Interest Declaration Form and submit with this application.

## (Q2.5) Staff training/credentialing

Please state if extra training/credentialing would be required at NT Health site(s), please describe type of training and who will provide them (i.e. sponsor)

If any associate investigators/research project staff perform any research activities that are outside of their scope of clinical practice, section 21 would need to be completed and signed by their authorising delegate (i.e. Executive Director of Medical Services, Executive Director of Nursing and Midwifery or Executive Director of Allied Health, etc.)

## (Q2.6) Project Coordinator/Contact Person

Please insert the details of the project coordinator or the contact person for this study, i.e. research nurse coordinator/clinical trial coordinator/research nurse (only complete if different from site PI)

# Project site(s)

## (Q3.1) Project/Study site(s)

Please tick appropriate answer

## (Q3.2) Teletrial

Please specify is this is a Teletrial project. If yes, please specify which NT Health site(s) will be the primary or satellite site(s). NT Teletrial team will get in touch for additional requirement to conduct a teletrial. For more information in regards Teletrial, please refer to our NT Health RGO website or national website [here](https://australianteletrialprogram.com.au/)

## (Q3.3) NT Health site(s)

Please tick the relevant NT Health site(s) that you are requesting research activities to occur within. An SSA needs to be completed for each Regional Heath Service where the project will be conducted. In the instance where proposed research is to be conducted across multiple regions, an SSA for each region is required. For research projects involving Population and Primary Health Care (PPHC), an SSA should be submitted to the RGO, whereby the RGO will arrange for the research proposal to have the relevant endorsements and review conducted. Each clinic you are considering as a project site within the Northern Territory remote [Primary Health Care Centre(s](https://nt.gov.au/wellbeing/remote-health/remote-health-services)) (PHCC) will need to be individually listed per region. Please note the SSA form is the initial document required to commence the research approval process. This information will be provided to the dedicated officer within PHCC who will follow internally processes to seek the required approvals for research to occur within an individual PHCC.

## Participants

(Q4.1) Please identify the target population of the research project at NT Health site(s) (i.e. children and young people, pregnant women, Aboriginal and Torres Strait Islander, NT Health Staff, etc.). Where studies are targeting health care workers, please consider them as the participants.

(Q4.2) Please record the total number of participants to be recruited for this research project at NT Health site(s)

(Q4.3) Please indicate the expected number of participants to be recruited for each NT health site(s) (include hospitals and PHC sites). Please add the number of years that recruitment is expected to occur for, if this is a registry that will continue to recruit you can write ‘indefinitely’.

## Resources

## (Q5.1) Site – Hospital activities

1. Please state how the project staff plan to identify potential participants for the research project.
2. Please state which wards or departments that the project will be performing research activities (i.e. ward 6A, outpatient clinic, emergency department, ICU, AWCCC).

Nurse Unit Manager/s must be consulted and the relevant correspondence/signatures needs to be submitted to the RGO

1. If the project is expecting to use clinic equipment such as ECG machines, blood pressure machines, intravenous infusion pumps etc., please tick yes and specify what equipment needed and if this will impact on the delivery of care to other patients. Please also comment on how you will ensure that this will not impact or lead to a shortfall of available equipment for current inpatient care.
2. If the project is expecting assistance or research activities to be undertaken by NT Health ward staff not specifically employed to perform research project activities, please tick yes. Please also indicate if this will be paid or in-kind support. As this may impact the workload of wards staff, you are required to seek written support from the Nurse Unit Manager, this can be an email of support. Please ensure that the amount of research activity expected is transparent during discussions.
3. If it is expected that the project will be utilising an Aboriginal Liaison Officer (ALO) for the conduct of research activities, please tick yes. Please also indicate if this will be paid or in-kind support. As this will impact the workload of the ALOs across the service, you will need to seek written support from the Aboriginal Liaison Office Manager, this can be an email of support.
4. If you require additional office/desk space specifically for this study, please tick yes. You will need to negotiate the additional office or desk space with the relevant authority and provide the relevant correspondence on what is agreed upon to the RGO.
5. Please add any additional support or resource requirements that have not been mentioned but are essential for the conduct of the project within the site.

## (Q5.2) Site – PHC activities

**General Statement**: All clinics within the Northern Territory are extremely busy with delivering primary health care needs to clients, in addition clinics are constantly accommodating regular specialist visits. Therefore, access to a clinic room, clinic staff, and/or clinic equipment is at the discretion of the clinic manager.

1. Please state how the project staff plan to identify potential participants for the research project.
2. Please state how the project staff plan to locate potential or active participants within the community, and if project visits are occurring within an NT Health clinic, how you plan for the participant to get to the clinic for their project visit/follow-up.
3. If you are planning on performing project visits within the clinics, please tick yes. Please also provide further information on what research activities you are planning to do within the clinic and for how long you are expecting that you will need the space. Please note that space is not freely available in clinics so if alternate arrangements can be made that don’t impact the safety of the participant then this should be considered. If this is not possible, then please be considerate of the frequency and length of project visits in terms of minimising impact on the day to day activities of the clinic.
4. If the project requires access to any clinical equipment such as ECG machines, blood pressure machines, thermometers, weigh scales, intravenous infusion pumps etc., please tick yes. Please also list the equipment that will be required. Please note that equipment may not be available or the room where the equipment is kept may not be available. Where possible, project team should supply their own equipment to avoid disappointment.
5. If the project requires PHCC staff to perform any protocol activities, please tick yes. Please also provide details of research activities that the PHCC staff may be asked to perform. Please ensure that you are transparent in your requirements.
6. Please add any additional support or resource requirements that have not been mentioned but are essential for the conduct of the trial within the clinic.

## Access to information and data

(Q6.1) Please tick the patient clinical management systems required for any external researchers to fulfil the requirements of this specific research project:

* No external researcher - If all researchers are NT Health employed.
* External researchers but access not required – If not accessing medical records.
* Please tick all relevant clinical management system.
* Site PI will need to contact RGO for external researchers access request form.

(Q6.2) Fees are associated with external access, therefore external staff access will be charged to a nominated cost centre by the site PI. It is the site PI’s decision to recover or absorb the costs.

(Q6.3) Please indicate the length of time that project documents such as the site investigator files, medication accountability records, participant consent forms and data collection forms, etc. will need to be kept for before they can be potentially destroyed (maximum # of years or # of years post publication). If this is not required, please tick N/A.

(Q6.4) Please indicate the length of time that participants hard copy medical records are required to be kept as per above. If this is not required, please tick N/A.

## Pharmacy – investigational drugs

(Q7.1) If your research project will involve administration of a medicinal product (investigational drug), please tick yes. If this does not involve medicines, please tick No and go to Q8.1

(Q7.2) Please indicate if the research project is conducted under a

* Clinical Trial Notification [CTN](https://www.tga.gov.au/clinical-trials) scheme – a trial of any medicine or device (or its software) not entered on the Australian Register of Therapeutic Goods (ARTG) including any new formulations of existing product or any new route of administration (i.e. off label usage or new indication); or a
* Clinical Trial Approval [CTA](https://www.tga.gov.au/clinical-trials) scheme -TGA’s approval to supply unapproved therapeutic goods in Australia via a clinical trial despite the therapeutic goods not being entered in the Australian Register of Therapeutic Goods. If the medication is being used within its licenced indication then please state this.

(Q7.3) Please indicate if the project will require any additional pharmacy services above standard care at NT Health site

*If yes, please tick all additional services that you will be requiring from the NT Health Pharmacy Department. Please ensure that you speak with the relevant Head of Department. The relevant head of Department can either sign the SSA form (section 16) or provide an email endorsement. Email endorsement will need to have full project title and describe all resources and support agreed to be provided by the relevant department. Please contact RGO if unsure of the authorising delegates for endorsement.*

 (Q7.4) Please indicate if the project funds will cover the costs of the study/trial medications and additional pharmacy services. If not, please also comment on who will cover the additional costs. If the division under which the research is occurring is expected to cover the costs this will need support from the divisional head. Please forward the relevant correspondence to the RGO.

(Q7.5) If applicable, please advise if any Non-NT Health Pharmacy will be performing some or all services.

If yes, please provide the name of the external organisational and details on their involvement at NT Health site

(Q7.6) Please indicate how the study/trial medication will be ordered for administration at an NT Health site or tick no and provide comment on the process that will occur.

The RGO will be able to provide advice on the correct pharmacy/pharmacist that you will need to liaise with.

*Pharmacy fees may be applicable to the research project, please* [*click here*](https://health.nt.gov.au/data-and-research/nt-health-research/fee-schedules)

## Radiology – medical imaging and nuclear medicine

(Q8.1) If your research project will require additional medical imaging above standard care at NT Health site, please tick yes. If no, please go to Q9.1

*If yes, please tick all additional services that you will be requiring from the NT Health Radiology Department. Please ensure that you speak with the relevant Head of Department. The relevant Head of Department can either sign the SSA form (section 16) or provide an email endorsement. Email endorsement will need to have full project title and describe all resources and support agreed to be provided by the relevant department. Please contact RGO if unsure of the authorising delegates for endorsement.*

(Q8.2) Please indicate which additional services/test(s) will be performed as part of this study, we require the number of additional tests per year over the number of years. If this test(s) is not covered by the project funds, please comment on who is expected to cover this cost. If the division under which the research is occurring is expected to cover the costs this will need support from the divisional head. Please forward the relevant correspondence to the RGO on this agreement.

Please also indicate if the project will require pulling or duplicating images, images to be de-identified or in bulk. If yes, please provide detail such as the number of duplicates across how many participants.

*Nuclear medicine and Radiology fees may be applicable to the research project, please* [*click here*](https://health.nt.gov.au/data-and-research/nt-health-research/fee-schedules)

## Pathology – Territory Pathology – NT Department of Health

(Q9.1) If your research project will require additional pathology service above standard care at NT Health site (i.e. pathology collection that is additional to routine care, additional testing requirements performed on pathology specimen that was collected as part of routine care or additional storage requirements), please tick yes. If no, please go to Q10.1

(Q9.2) *If yes, please tick all additional services that you will be requiring from the Territory Pathology. Please ensure that you speak with the relevant Head of Department/Manager. The relevant head of Department/Manager can either sign the SSA form (section 16) or provide an email endorsement. Email endorsement will need to have full project title and describe all resources and support agreed to be provided by the relevant department. Please contact RGO if unsure of the authorising delegates for endorsement.*

(Q9.3) Please indicate if the project funds will cover the costs of the additional pathology services. If not, please also comment on who will cover the additional costs. If the division under which the research is occurring is expected to cover the costs this will need support from the divisional head. Please forward the relevant correspondence to the RGO.

It is recommended to avoid delays that you contact the Operations Manager Territory Pathology early in the research process to ensure feasibility and authorisation of the research, call 0437 918 911.

Please inform the RGO if you are entering into a separate service agreement with Territory Pathology.

*Pathology fees may be applicable to the research project, please* [*click here*](https://health.nt.gov.au/data-and-research/nt-health-research/fee-schedules)

## Research Agreement

If your study involves an agreement between NT Health and any other party, then this agreement must be submitted to the RGO for review.

This includes any confidentiality disclosure agreements, research collaboration agreements (for example, funding agreements, head agreements), data sharing agreements, or contracts. These agreements need not adhere to a specific format and can be based on local templates of other institutions or organisations. Please be aware that non-standard clinical trial and collaborative research agreements will require legal counsel which can lengthen approval times by a minimum of three months. The RGO will arrange legal review on your behalf as required. The NT prefers to use the relevant [Medicines Australia Clinical Trials Agreements template,](https://medicinesaustralia.com.au/policy/clinical-trials/clinical-trials-research-agreements) the RGO will insert a signature block for the institution and standard schedule 4 special conditions required for the NT. Please speak with the RGO to ensure a timely approval process.

For medical device research, the templates for [contracts and indemnities](https://www.mtaa.org.au/clinical-investigations-research-agreements) are maintained by Medical Technology Association of Australia, this provides a suite of commercially sponsored templates **only**.

The NT of Australia is the legal entity that can enter into research agreements. Where fees are chargeable, the appropriate fee will be charged as outlined in the NT Health fees schedule.

|  |
| --- |
| MA and MTAA Clinical trial research agreement template – institutional details |
| Name of Institution  | Northern Territory of Australia, through its agency the Department of Health – NT Regional Health Service |
| Address | 105 Rocklands Drive, Tiwi, NT 0810 |
| ABN | 84 85 734 992 |

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## Indemnity and Insurance

The NT of Australia, care of its agency the Department of Health (DoH) provides self-insurance.

#### 4.11.1 Indemnity – NT Health employees

#### NT Health employees conducting a research project in the capacity of their employment with NT Health are automatically covered by NT DoH self-insurance arrangements. Indemnity - commercial sponsor

For commercially sponsored clinical trials or contract research organisations (acting on behalf of the sponsor), the sponsor must supply evidence of its insurance cover. A sponsor’s insurance cover must indemnify the local site, investigator and research staff. For all commercially sponsored clinical trials, use of the [Medicines Australia standard indemnity form](https://medicinesaustralia.com.au/policy/clinical-trials/indemity-and-compensation-guidelines) is the preferred form executed on behalf of the sponsor prior to the site specific assessment (SSA) submission. If a sponsor has not signed the indemnity form prior to SSA submission, the RGO must be provided with an executed copy prior to final SSA authorisation.

**The RGO will review ‘indemnified party’ details and insert the signature block for the ‘institution’ prior to approval for sign off, please contact the RGO.**

The RGO will arrange for the indemnity to be executed on behalf of the institution, please note the executed version will be sent out with the authorisation email.

#### Indemnity - collaborative research group

For CRGs the indemnity arrangements are outlined in the clinical trials research agreement, in general, the NT of Australia will cover NT Health employees conducting research activities under a CRG, however if the research activities are performed by a non-NT Health employee on NT Health facilities or with NT Health confidential data the non-NT Health employee’s organisation must provide indemnity for their employee.

#### Certificate of currency - requirements for all clinical trials

For clinical trials, the entity that has accepted the role of the sponsor will be required to submit a certificate of currency (CoC) to the RGO. This insurance will indemnify the participants involved in the research project and requires submission to the RGO. Please include name of insurer and expiry date.

## Biosafety, chemical and radiation safety

All research that involves biosafety or radiation must comply with the relevant requirements.

#### Regulation of gene technologies and related therapies

By law to abide by the Commonwealth scheme for the regulation of genetically modified organisms (GMO) in Australia as defined in the Gene Technology Act 2000 (Cth) and the Gene Technology Regulations 2001. Dealing with a GMO without appropriate authorisation under the Act is an offence, and subject to penalties.

For further information, go to the [Office of the Gene Technology Regulator](https://www.ogtr.gov.au/) (OGTR).

The RGO must be supplied with an approval letter from the Institutional Biosafety Committee and a licence for dealings with GMO that has been reviewed and approved by the Human Research Ethics Committee of the Norther Territory Department of Health and Menzies School of Health Research (NT HREC).

#### Ionising radiation

A research project involving the use of ionising radiation must be noted by HREC according to the Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (ARPANSA, 2005).

For multi-centre trials under NMA where ethical review is undertaken by a single central HREC then it is the responsibility of the Coordinating Principal Investigator to submit one radiation safety risk assessment for the lead HREC. This will be compared to the local sites radiation risk category. For further information please visit [Australian Radiation Protection and Nuclear Safety Agency](https://www.arpansa.gov.au/about-us/advisory-council-and-committees/radiation-health-committee/trials-statement).

For single site ethical review, the radiation safety in research involving the exposure of human volunteers to ionising radiation is the responsibility of the institution at which the research is being undertaken. The PI at each site is responsible for ensuring that any advice provided by a Medical Physicist in relation to a particular research project is complied with in full.

The site PI is required to either:

* provide a letter stating that radiation exposure is part of normal clinical management/care
* if radiation exposure is **additional**to that received as part of normal clinical management / care, an independent assessment report by a Medical Physicist of the total effective dose and relevant organ doses including risk assessment.

In addition, you will be required to seek support from the Head of the Medical Imaging Department.

## Funding

(Q13.1) Please specify sponsor name

(Q13.2) Please tick the appropriate Sponsor type

Commercial Sponsor: Industry sponsored (i.e. pharmaceutical or device companies). The sponsoring pharmaceutical or medical device company must be an Australian entity. This could be an Australian pharmaceutical or medical device company or an Australian subsidiary of an international pharmaceutical or medical device company.

Collaborative Research Group (CRG): This is often NHMRC funded studies or not-for profit collaborative research groups.

Investigator Initiated Group: These studies can be driven by one investigator or it can be a number of investigators. The study is generally unfunded or insufficiently funded and rely on in-kind support.

Institution: Studies that are conducted and supported by the Institution.

University: Studies that are conducted and supported by the University.

(Q13.3) Please indicate if the research project has received funding. If any funding was received, please tick yes even if this was only partial funding. If no, go to Q14.1

(Q13.4) Please indicate the funding source, this may be more than one funder.

(Q13.5) Payments are generally known but in some instances, this can still be in negotiation at the time the SSA is completed. If this is the case, please tick still negotiating. Otherwise, please specify the estimated funding to be received for this project at this site – please include amount to be received either per year or per participant. You will be required to provide further information prior to SSA and payments should be included in the agreement.

Please note to assist with negotiations, please ensure that your funder or funding source is aware of the current [fee schedule](https://health.nt.gov.au/data-and-research/nt-health-research/fee-schedules) listed on the NT Health website.

(Q13.6) Please indicate if the expected funding to be received for this site will cover the costs of the research. If not, please specify how the shortfall costs will be absorbed (i.e. dedicated research staff that work across a number of trials that can cover the shortfall or in-kind support). Please forward the relevant correspondence to the RGO on this agreement.

(Q13.7) The [fee schedule](https://health.nt.gov.au/data-and-research/nt-health-research/fee-schedules) (on the NT Health website) lists associated costs for research activities and governance review, how monies will be invoiced and managed. Please note the fees are applicable to Commercial Sponsor Studies and/or External Research Funding (i.e. CRG). Please complete details in this section for billing purposes.

**(Q13.8) Financial oversight and authorisation**

For any research project that receives funding, site PI would need to nominate a responsible person (i.e. unit finance officer) for this site who will manage the funding provided for the project, and what cost centre/s funds will be paid into and drawn from. This would need to be discussed with the relevant authorising delegates (i.e. divisional performance managers).

*Please contact RGO if unsure of the authorising delegates.*

## Intellectual Property (IP)

(Q14.1) If there is a possibility of the development of new intellectual property with the potential of commercialisation as a result of this project being undertaken at this site, please tick yes.

(Q14.2) If yes to 14.1, please outline the intellectual property rights to within the Agreement (i.e. owned Solely by the Sponsor/CRG, owned Solely by NT Health, shared between parties).

(Q14.3) If it is expected that Intellectual Property rights will be retained by the site PI/NT Health, we will require further information. Please indicate who will be responsible for financially supporting the development of this IP should the research generate new knowledge and/or breakthroughs. If unsure, please contact the RGO and we can arrange for advice from legal services as required.

## Dissemination of outcomes

(Q15.1) Please indicate how the results of the study will be disseminated/implemented to relevant staff within the NT Health Services (i.e. ward inservices, ward/grand rounds, etc.)

(Q15.2) Please indicate how the research results will be fed back to the participants that is specific to urban and/or remote as applicable. If no participants or waiver of consent, please write N/A.

## Departments/Services Endorsements

As part of our governance approval process, approval from the Head/s of Department/s or Service/s is required. Please provide all required signatures within this section or a separate email of support/endorsement. If endorsed via email, their email should include full project title and describe all resources and support agreed to be provided by the relevant department for this research project (i.e. pharmacy, pathology, radiology, wards nurse managers, etc).

Where the Principal Investigator for the research project is also the Head of Department, support must be sought from the person to whom the Head of Department is responsible. Investigators must not approve their own research on behalf of the Health Service.

## Supporting Documents

Please attach each supporting documents separately with the completed SSA form. Files should be named consistently to include project title/acronym, document type, version and date (dd/mm/yyyy).

### Site Specific requirements for participant information sheet and consent form (PISCF) – NT Health RGO details

### The PISCF require the insertion of the NT Government logo where NT Health is the site and a paragraph informing participants how to contact the RGO. Please use the below paragraph as a guide for insertion into the participant information statement (PIS). This is in addition to the reviewing ethics and site PI contact details.

### **The conduct of this study at [name of site] has been authorised by Northern Territory Health. Any person with concerns or feedback (complaints or compliment) about the conduct of this study may contact the NT Health Research Governance Officer on 08 8922 7764 or email****nthealth.rgo@nt.gov.au****and quote reference number [insert SSA reference number].**

## Document submission checklist

This is a guide of the required documentation for the site specific assessment submission.

## Declaration by Site PI

The role of the NT Health Research Governance Office is to ensure research is conducted according to established ethical principles, guidelines for the responsible research conduct, relevant legislation, regulations and NT Health policies.

NT Health authorises the PI to assume ultimate responsibility for the scientific, technical and administrative aspects of the research project, even when certain tasks have been delegated to other members of the research team.

By signing this declaration, you declare that you have read and accepted the NT Health site PI responsibilities [here](https://health.nt.gov.au/data-and-research/nt-health-research/site-principal-investigator-responsibilities) for the oversight of all research staff activities

## Recommendation by most relevant

Any division or department that is involved in the research must endorse the research being conducted in their department. This includes departments that are actively involved in the research. It may also include departments that are not actively involved, but will experience some impact from the conduct of research, for example, participants will be recruited from the department.

All relevant divisional or department heads must confirm support either by email or a letter of support.

It is a conflict of interest for any person who is an Investigator, whether as the Principal Investigator or Associate Investigator, to also provide endorsement as the head of department. In instances where the head of department is an Investigator, the endorsement must be provided by the next highest level of authority. For example, where a department head is also the Principal Investigator, the divisional head must provide endorsement.

The role of Unit Heads and/or Co-Director is to assess:

* There are suitable and adequate facilities and resources for the research project to be conducted at this site.
* The research is relevant to the site and aligns with the NT Health strategic goals.
* The organisation’s benefit of participating in the research is consistent with the resource contribution.
* The research translation strategy is demonstrated and will provide evidence based information for improving patient outcomes, clinical care or service delivery.
* All external researchers/students involved in the research project have the skills, training and experience necessary to undertake their role.
* All NT Health researchers/students involved in the research project have the skills, training and experience necessary to undertake their role.
* There is no conflict of interest for the researcher’s or that the declared conflict of interest is acceptable.
* There is evidence of compliance with indemnity requirements.
* Requirements for access to organisational data are clear and comply with legislative and NT Health policy requirements.
* Data management, privacy and confidentiality requirements are described, and comply with legislative requirements.

*Please contact RGO if unsure of the authorising delegates.*

## Recommendation by relevant professional lead

Please only complete this section where the research project is related to Professional Practice; if any investigator or research personnel would perform any research activities that are outside of their scope of clinical practice. This section would need to be completed and signed by their authorising delegate (i.e. Executive Director of Medical Services, Executive Director of Nursing and Midwifery or Executive Director of Allied Health, etc.)

*Please contact RGO if unsure of the authorising delegates.*

## Recommendation by Institutional Head

The role of Institutional Head is to assess:

* There is a clear organisational benefit of participation in the research.
* The research is consistent with the strategic objectives of the organisation.
* The research project and resource implications are within the allocated budget of the service.

*Please contact RGO if unsure of the authorising delegates.*

## Final authorisation by RGO

This will be the final review for the SSA form post support by all other relevant delegates. The RGO will facilitate the final authorisation for the research which is provided by the Executive Director of Research. The Site PI will be notified by the RGO of the outcome.